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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>February 19, 2010</u> Signature <u>[Signature]</u> Typed or printed name <u>Harold E Cutler</u>	Application Number 10/593, 172	Filed September 15, 2006
	First Named Inventor Harold E Cutler	
	Art Unit 3771	Examiner Colin Stuart

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☒ applicant/inventor.
- ☐ assignee of record of the entire interest.
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.
(Form PTO/SB/96)
- ☐ attorney or agent of record.
Registration number _____
- ☐ attorney or agent acting under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

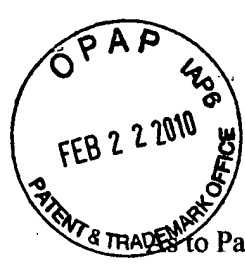
[Signature]
Signature
Harold E Cutler
Typed or printed name
224-848-0302
Telephone number
February 19, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required.
Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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ARGUMENTS FOR APPEAL

to Paragraph 3 and rejection of Claims 6, 12, 15 and 16:

“Rejection on obviousness grounds cannot be sustained by mere conclusory statements: instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *KSR v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007)(Quoting from *in re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2007)

Examiner has provided no reference to the use of a palate lifter in the verbiage of either the Pivovarov patent or application, nor has examiner provided reference to any publication in the applied art referencing the combination of two components similar to a “tongue receptacle” and a “soft palate lifter” in a single device.

In view of this deficiency, examiner imputing the presence of a palate lifter in Pivovarov ‘430 or ‘804 does not provide the required articulated reasoning with rational underpinning but, rather, is merely an assertion having no basis in the applied art. Appellant finds reversible error in the rejection of Claims 6, 12, 15-17

“An inherent characteristic must be inevitable, , and not merely a possibility or probability” *in re Oerlich*, 666 F.2d 578, 581 (CIPA 1981)

There exists no evidence or suggestion in Pivovarov of addressing the soft palate. His approach is to solve the problem by controlling the movement of the tongue such as it can be controlled by encompassing the frontal portion of the tongue within the curved “tongue receptacle” formed by the presence of both “Lobe A” and “Lobe B” in unison. There is no mention of a “soft palate member” or “soft palate lifter” to be found anywhere within the text of either Pivovarov ‘430 or ‘804 nor is there such reference, or component found in any of the prior art cited the within patents referenced within Pivovarov, or within the patents referenced within the Pivovarov references. There is no reference to addressing the soft palate in Jackson (5174284), Meah (6,257,238), Robinson et al.(2003/0089371), or Wright (2006/0207597 all cited as pertinent, although none are pertinent to the art of treating sleep apnea or snoring, nor does examiner reference any publications within the applied art suggesting addressing both the tongue and soft pallet simultaneously. The fact is that such references do not exist as soft palate members, or lifters were, and are to this day, considered ineffective in addressing symptoms of sleep apnea and snoring. They are also thought to be difficult to acclimate to due to the “gag reflex”. Therefore, as soft palate lifters are not a part of the culture of the applied art, employing such a component, especially in a device designed and intended to address only the tongue, would not have been obvious to one of average skill in the art. As there is no soft palate member in Pivovarov, objections to “adjustability” and “independent operability” of same are mute. Appellant finds reversible error in the rejection of Claims 6, 12, 15-17

“A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of argument based on *ex post* reasoning” *KSR* 550 U.S. at 421.

Examiner points to Figs. 1 and 9 of ‘430 as the support for the assignment of the utility of ‘palate lifter” on “Lobe A” in Pivovarov. It should be noted that no soft palate is present in, or referred to, in either drawing (See Appendix, Figs. 1, 9), and if it were to be added to Fig. 9, it would be located at the very rear of the oral cavity, above the point where the tongue curves downward (not shown)...well beyond the intended reach of “Lobe A” by any reasonable interpretation of anatomy.

In the absence of foresight supported by direct and proper reference as stated above, and in view of the prominence of the soft palate lifter in the instant application, there is no propensity for examiner to find as obvious, or included, the unintended utility of “palate member” to “Lobe A” in Pivovarov ‘803 and ‘430 other than the application of hindsight after of having previously viewed the claims, specifications, and drawings contained in the instant application. For this reason, appellant finds reversible error in the rejection of Claims 6, 12, 15-17.

As to Paragraph 4 and Rejection of Claim 16:

“During examination, claim terms must be given their broadest reasonable construction consistent with the Specifications.” Health and Fitness, Inc.”, 496 F 3d 1374, 1378-79 (Fed. Cir. 2007).

In Pivovarov, it is apparent that Lobe “B” is to be positioned *under the front portion* of the tongue as part of the function of “Structure 12” as “tongue receptacle” which would tend to inhibit *forward* movement of the tongue. It would not be obvious, then to one of ordinary skill in the art, to abandon completely that form and function and lay the entire structure 12 *atop* the tongue extending it rearwards and downward *behind the tongue*, which would tend to inhibit *rearward* movement of the tongue as described in the Claim 16, and consistent with the Specifications [036] of the instant application. As none of these changes are consistent with the Specifications in Pivovarov, Appellant finds reversible error in examiner’s rejection of Claim 16 under “Health and Fitness, Inc.”, as well as *in re* Orlich and *KSR v Teleflex* as referenced above.

Re: Response to Arguments

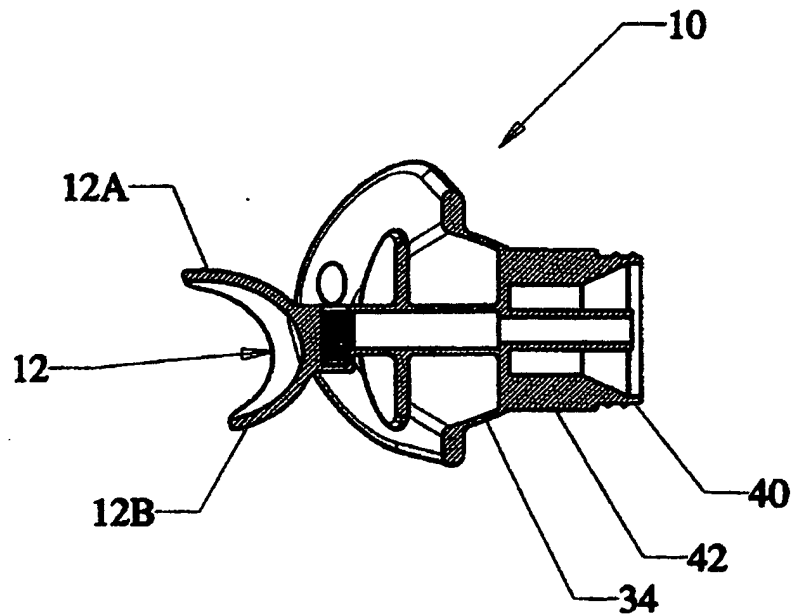
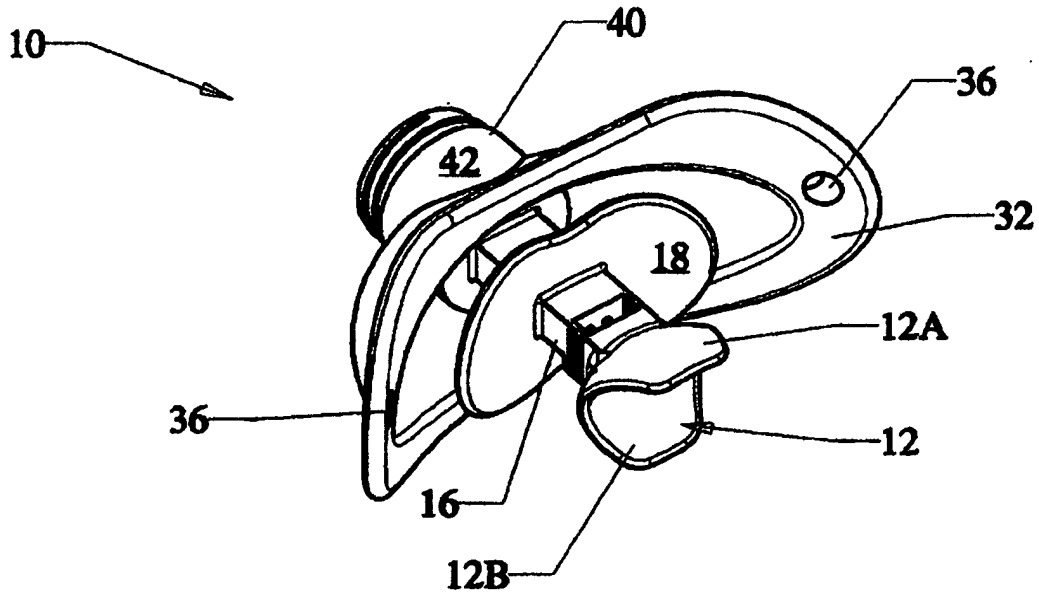
In examiner’s Response to Arguments, examiner writes in defense of the assignment of function as “palate member” to “12A” of Pivovarov, “...the anatomy of the human differs from person to person and a smaller or adult or child’s soft palate would be affected by the device”. There is no stated purpose in Pivovarov for “12A” to affect the soft palate, and no limitation as to size of the user of the device. Examiner’s argument that accidental and unintended contact with the soft palate due only to the size of a user of a certain stature is sufficient foundation for applying the function of “palate member” to “12A” is improper reasoning under *in re Orlich* as well as *KSR v Teleflex* as referenced above. Appellant finds reversible error in the rejection of Claims 6, 12, 15-17.

The description “ending in a declined portion” was added to the description of the palate member in the instant application to differentiate it from component “12A” in Pivovarov. This was suggested by examiner during the interview on June 16, 2009. In the final rejections, examiner defines “12A” of ‘430 as having a “declining upwards angled portion” and uses this confusing interpretation as a basis for rejection. The portion cannot be “angled upwards” and declining, or angled downwards (as presented in Claims 6 and 12, and supported by the Figs.4 and 5 in the instant application), at the same time. In support of the rejection, examiner points to Fig. 1 of ‘430 which is drawn in perspective with the entire device on a pronounced downward angle (Appendix, Page 1). Even so, it is obvious that there is no portion of “12A” that is declined, or angled downward in the direction the rear of the oral cavity. The lack of a “declined portion” is further exemplified by Fig. 4 of ‘430 (Appendix, Page 1) which is the only figure in Pivovarov drawn on a true horizontal axis, as well as Fig. 9 of ‘430 (Appendix, Page 2). Examiner further states that the “soft palate member” in Pivovarov “maintains contact with the soft palate of the wearer”. Figure 9 shows no such relationship as a soft palate is not even depicted in the drawing.

“TO ESTABLISH ANTICIPATION, EVERY ELEMENT AND LIMITATION OF THE CLAIMED INVENTION MUST BE FOUND IN A SINGLE PRIOR ART REFERENCE ARRANGED AS IN THE CLAIM.” Karsten MFG Corp v. Cleveland Golf Co, 242 F .3d 1376, 1383(Fed Cir. 2001).

Examiner fails to adequately support the nomenclature of “soft palate member” onto “Lobe A” as required under ” *KSR v. Teleflex, Inc.*, 550 U.S. 398, 418 (2007), and *KSR* 550 U.S. at 421 specifically, and *in re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2007), and *in re Oerlich*, 666 F.2d 578, 581 (CPPA 1981) as referenced above. In view of this deficiency, appellant asks that the rejection of Claims 6, 12, 15-17 be reversed.

As no cited patent or application contains a “soft palate lifter”, or a “tongue member” designed to inhibit *rearward* movement of the tongue, and there is no evidence presented to indicate that one of average skill in the art would have found as “obvious” the many changes necessary to incorporate those elements and functions within the prior art, Appellant asks that the device described in Application 10/593, 172 be found, in total, to be unique and unanticipated against the prior art cited and the rejection of Claims 6, 12, 15, 16, and 17 be reversed.

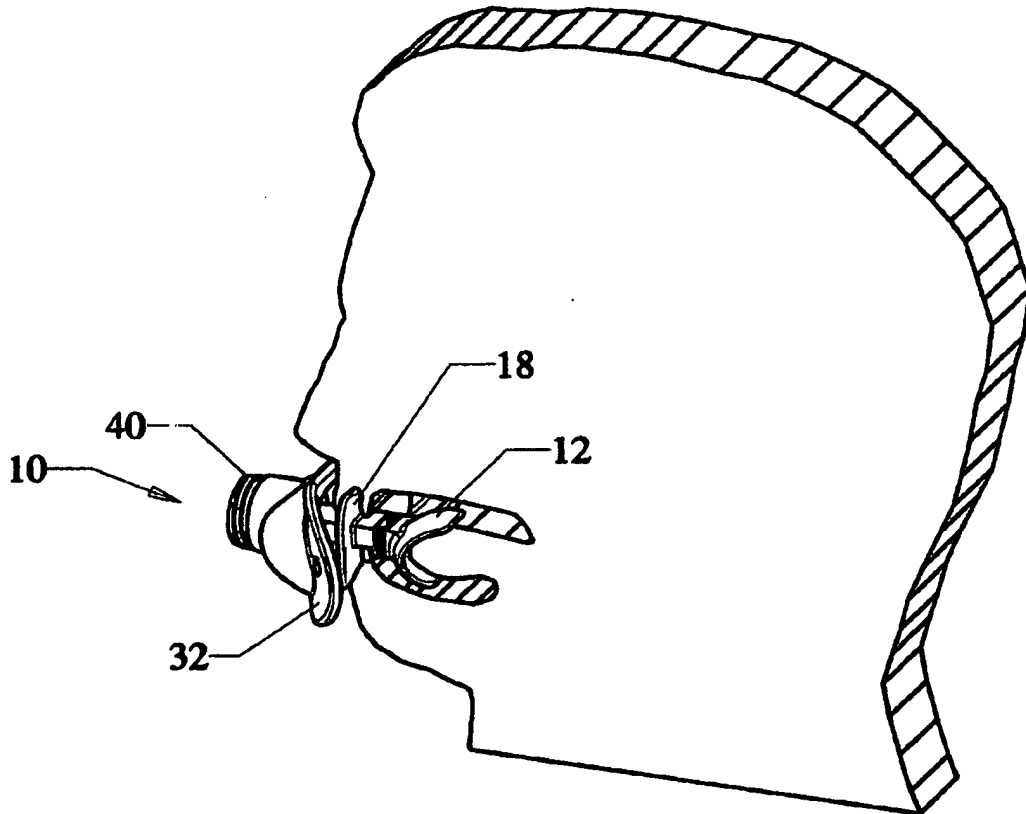


No "declined portion on "12A"

APPENDIX
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No “declined portion” on “Lobe A” of Structure 12.

Lobe “B” is clearly under the tongue.

As positioned, the cup formed by Lobes A and B of structure 12 would keep the tongue from moving forward and provide no restriction to rearward movement.

There is no soft palate depicted.

If the soft palate was shown and properly located, it would be above the very rear of the tongue where it curves downward. That is at a point farther into the oral cavity than is depicted in this drawing.